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JC04 Rec'd PCT/PTO 13 APR 2001

PTO-1390 (Modified) (11-99)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER <b>MCA-433 PC/US</b>	
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371				U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR <b>09/807592</b>	
INTERNATIONAL APPLICATION NO. <b>PCT/US99/30141</b>		INTERNATIONAL FILING DATE <b>17 DECEMBER 1999</b>		PRIORITY DATE CLAIMED <b>17 DECEMBER 1998</b>	
TITLE OF INVENTION <b>HOLLOW FIBER SEPARATION MODULE AND METHODS FOR MANUFACTURING SAME</b>					
APPLICANT(S) FOR DO/EO/US <b>PEARL, ET AL.</b>					
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:					
<p>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</p> <p>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).</p> <p>4. <input checked="" type="checkbox"/> A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c) (2))</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau).</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> has been transmitted by the International Bureau.</p> <p style="margin-left: 20px;">c. <input checked="" type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input type="checkbox"/> A translation of the International Application into English (35 U.S.C. 371 (c)(2)).</p> <p>7. <input checked="" type="checkbox"/> A copy of the International Search Report (PCT/ISA/210).</p> <p>8. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau).</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> have been transmitted by the International Bureau.</p> <p style="margin-left: 20px;">c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p style="margin-left: 20px;">d. <input checked="" type="checkbox"/> have not been made and will not be made.</p> <p>9. <input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).</p> <p>10. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).</p> <p>11. <input checked="" type="checkbox"/> A copy of the International Preliminary Examination Report (PCT/IPEA/409).</p> <p>12. <input type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).</p> <p><b>Items 13 to 20 below concern document(s) or information included:</b></p> <p>13. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>14. <input checked="" type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>15. <input checked="" type="checkbox"/> A <b>FIRST</b> preliminary amendment.</p> <p>16. <input type="checkbox"/> A <b>SECOND</b> or <b>SUBSEQUENT</b> preliminary amendment.</p> <p>17. <input type="checkbox"/> A substitute specification.</p> <p>18. <input type="checkbox"/> A change of power of attorney and/or address letter.</p> <p>19. <input checked="" type="checkbox"/> Certificate of Mailing by Express Mail</p> <p>20. <input checked="" type="checkbox"/> Other items or information:</p>					
<p>Authorization to charge fees to deposit acct. no. 133577 (fee pages in duplicate); reference (s) cited in PTO 1449; postcard, Written Opinion and response</p>					

U.S. APPLICATION NO. (IF KNOWN, SEE 3)

09/807592

INTERNATIONAL APPLICATION NO.

PCT/US99/30141

ATTORNEY'S DOCKET NUMBER

MCA-433 PC/US

21. The following fees are submitted..

**BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :**

- ☐ Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2) paid to USPTO and International Search Report not prepared by the EPO or JPO ..... \$970.00
- ☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO ..... \$840.00
- ☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... \$690.00
- ☐ International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) ..... \$670.00
- ☒ International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) ..... \$96.00

**ENTER APPROPRIATE BASIC FEE AMOUNT =**

\$96.00

Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492 (e)). ☐ 20 ☐ 30

\$0.00

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	25 - 20 =	5	x \$18.00	\$90.00
Independent claims	4 - 3 =	1	x \$78.00	\$78.00
Multiple Dependent Claims (check if applicable).			<input type="checkbox"/>	\$0.00
<b>TOTAL OF ABOVE CALCULATIONS =</b>				<b>\$264.00</b>

Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28) (check if applicable). ☐

\$0.00

**SUBTOTAL =**

\$264.00

Processing fee of \$130.00 for furnishing the English translation later than months from the earliest claimed priority date (37 CFR 1.492 (f)). ☐ 20 ☐ 30

\$0.00

**TOTAL NATIONAL FEE =**

\$264.00

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable). ☐

\$0.00

**TOTAL FEES ENCLOSED =**

\$264.00

Amount to be refunded	\$
charged	\$

- ☐ A check in the amount of \_\_\_\_\_ to cover the above fees is enclosed.
- ☒ Please charge my Deposit Account No. 133577 in the amount of \_\_\_\_\_ to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- ☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 133577. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

John Dana Hubbard  
Millipore Corporation  
80 Ashby Road  
Bedford, MA 01730

SIGNATURE

John Dana Hubbard

NAME

30,465

REGISTRATION NUMBER

DATE

## CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)

Docket No.

Applicant(s): Pearl, et al

MCA-433 PC/US

Serial No.

Filing Date

Examiner

Group Art Unit

NOT YET ASSIGNED

April 13, 2001

NOT  
ASSIGNED

YET

NOT  
ASSIGNED

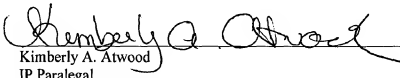
YET

Invention:

HOLLOW FIBER SEPARATION MODULE AND METHODS FOR MANUFACTURING SAME

I hereby certify that this Transmittal Letter with Calculation of Fees (2 pp); Unsigned Declaration (2 pp); International Search Report (6 pp); PCT Examiner phone call (2 pp); Notification of transmittal of International Preliminary Examination Report (5 pp); Response to Written Opinion (3 pp); Written Opinion (8 pp); Transmittal of Information Disclosure Statement (2 pp); Information Disclosure Citation (1 p); References AA-AD; Postcard; with authorization to charge deposit account No. 13-3577; Certificate of Express Mailing EL634001942US

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: The Assistant Commissioner of Patents and Trademarks, Washington, D.C. 20231 on April 13, 2001.

  
Kimberly A. Atwood  
IP Paralegal  
Millipore Corporation

EL634001942US

"Express Mail" Mailing Label Number

09/807592

JCO3 REC'D PCT/PNO

13 APR 2001

Attorney Docket No. MCA-433 PC

IN THE UNITED STATES RECEIVING OFFICE

APPLICANT: Millipore Corporation

SERIAL NO.: PCT/US99/30141

INT'L FILING DATE: 17 Dec. 1999

INT'L PRIORITY DATE: 17 Dec. 1998

TITLE: HOLLOW FIBER SEPARATION MODULE  
AND METHOD OF MANUFACTURING SAME

EXAMINER: Sun Uk Kim

Assistant Commissioner of Patents  
Box PCT  
Washington, DC 20231

Response to Written Opinion

This Response is directed to the 17 October 2000 Written Opinion concerning the above-identified application.

Applicant makes this Response to highlight Examiner's failure to consider the claim element "designed to provide a specific performance output" in making its rejections of the claims of the present application. Applicant maintains that after Examiner properly considers this element in light of its definition in the specification and the failings of the prior art, the Examiner can only find the present invention novel and having an inventive step.

Statement of Invention

The present invention is directed to the production of multi-layered, hollow fiber filtration cartridges that are scalable **algorithmically**. Such work as currently claimed concerns a patentable improvement over the prior art. In particular, the presently claimed invention is patentable over the work described in the Belfort patent (U.S. Patent No. 5,626,758) which forms the basis of the Examiner's rejections under novelty and inventive step.

The present invention provides algorithms that allow one to produce multi-layered filtration cartridges that have a specific (ie, pre-determined) performance output. Unlike the invention disclosed in Belfort, which was directed to only prediction of the performance of a single layered device, Applicant has discovered how to adjust the variables from layer to layer to control performance of each subsequent layer of the device. This control allows Applicant to produce filtration cartridges that are **scalable without the need for trial and error**. Such a breakthrough provides a filtration cartridge that is much cheaper to produce because scalability is a critical issue in biological process applications. Applicant must demonstrate to the consumers of such filtration cartridges that performance at the lab (single layer device) is scalable to pilot (multi-layered) and process scale (multiple multi-layered devices). By eliminating the trial and error typically associated with creating pilot and process scale devices that are

scalable from the lab device, Applicant can produce a product that is cheaper to produce and does away with the need to run expensive validation runs.

**Discussion of Belfort**

Belfort does not disclose all the elements of the currently claimed invention and therefore is not a proper reference for a novelty rejection. It fails to provide any guidance on producing multi-layered devices with a specific performance output. It merely provides a picture of a multi-layered device. It fails to mention the number, winding angle or length of fibers that one would utilize in producing the subsequent layers of such a multi-layered device.

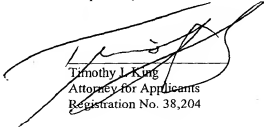
In Example VI (see Table IV) Applicant altered the number, length and winding angles of the hollow fibers used in the different layers of a multi-layered device of the present invention. Applicant did not use trial and error, rather Applicant utilized the algorithms it formulated to adjust these parameters to produce a specific performance output. **Belfort makes no mention of adjusting these parameters to provide a pre-determined and specific performance output for a multi-layered device.**

Since Belfort fails as an anticipatory reference and the other references are not directed to the use of Dean vortices, the additional references are not properly combined with Belfort and therefore not relevant to the present invention. Moreover, the combination of the references still does not disclose multi-layered hollow fiber filtration cartridges that have specific layer-to-layer performance outputs that were derived algorithmically.

**Conclusion**

Applicant respectfully requests the Examiner to reconsider and withdraw all rejections against the present application.

Respectfully submitted,



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December 18, 2000  
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